Exhibit A

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

DEBORAH A. BARBA and
THOMAS D. BARBA, her husband,

Plaintiffs,

v. C.A. No. N11C-08-050 MMJ

BOSTON SCIENTIFIC CORPORATION,
a Delaware Corporation,

Defendant.

BEFORE: HONORABLE MARY M. JOHNSTON, J. AND JURY

APPEARANCES:

PHILIP T. EDWARDS, ESQ.
Murphy & Landon
and
FRED THOMPSON, III, ESQ.
FIDELMA L. FITZPATRICK, ESQ.
BREANNE V. COPE, ESQ.
Motley Rice LLC
for the Plaintiffs

COLLEEN SHIELDS, ESQ.
Eckert, Seamans, Cherin & Mellott, LLC
and
MATTHEW D. KEENAN, ESQ.
Shook, Hardy & Bacon LLP
for the Defendant

TRIAL TRANSCRIPT
May 18, 2015

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is going to be laid for Dr. Parisian to testify on this issue. I will, however, be listening very carefully to whether or not that proper foundation is, indeed, going to be laid. And I want to again emphasize that Dr. Parisian has been permitted to testify as an expert on FDA and federal regulations.

Now, I have some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions that her opinions be based again on her expertise with FDA approval processes and federal regulations. So that is the first thing.

The second thing is with regard to the labeling motion. I am going to limit any training testimony to whether or not that is information that should have been provided to the physician. I'm not going to let Dr. Parisian talk about the type of training, whether training was adequate, I don't know whether she wants to get into that or not. That issue is only peripherally relevant to specific information.

I believe that there has been sufficient testimony by Dr. Carlson, and also as the parties have been placed on notice in the expert report to talk about

rates of occurrence, and whether that information should have been provided to Dr. Carlson. And it goes to his choice of products. It goes to failure rate. It goes to stiffness. That information is a proper subject of Dr. Parisian's testimony.

Now, it gets a little bit nuanced because it is clear that it is a valid argument by plaintiff, and a valid subject of evidence that certain information, including rates of occurrence, and permanency, and removal issues should have been given to the physician. So while I am cognizant of Boston Scientific's argument, I don't know how else the information could have been provided to the physician except through a DFU or the equivalent. And I do think that because of that, I am going to permit Dr. Parisian to say that the DFU should have included this type of information, but I'm also going to allow Boston Scientific to explore whether that information could have been provided in another manner. And, certainly, Boston Scientific can make the argument that it wasn't necessary that this particular information be provided in a DFU, but could have been provided in another manner, or wasn't necessary to be provided. I think it's a question of fact for the jury

as to whether or not this specific information could or should have been provided in the DFU.

Now, it is entirely possible in theory that upon examination and cross-examination the jury will find that this witness is just opining that this is information that should have been in the DFU and doesn't really have a basis for that in FDA regulations or law. That's entirely possible, could go either way. But I think it's a hotly disputed issue of fact as to whether or not this information should have been provided in this document and in this format. I'm going to let Dr. Parisian opine on that without going too far afield.

MR. KEENAN: There's two other quick issues, Your Honor.

THE COURT: All right.

MR. KEENAN: There is a document that counsel identified last night that he intends to use with Dr. Parisian. And it is on an issue that she's not disclosed on her reliance list. It wasn't subject of our deposition that we had with her. And in the most recent updated, truncated disclosure that we got about a month ago it's not identified in it either. And it is this question of sensitization. I objected to this last

Kelleher, I mean Stacey Davis. That means we have one alternate left, Daniel Kelleher.

Are we ready for the jury or do we need a break?

MR. THOMPSON: Your Honor, we're ready to go.

THE COURT: All right.

(Pause.)

(The jury entered the courtroom at 10:28 a.m.)

THE COURT: Good morning, everyone.

The plaintiffs may present their next witness.

MR. THOMPSON: Your Honor, we'd like to call Dr. Susan Parisian to the stand, please.

SUZANNE PARISIAN,

having been first called by the Plaintiff was sworn on oath, was examined and testified as follows:

MR. THOMPSON: Good morning Dr. Parisian.

THE WITNESS: Good morning Mr. Thompson.

DIRECT EXAMINATION

BY MR. THOMPSON:

Q. Dr. Parisian -- judge, may I approach?

THE COURT: Certainly.

BY MR. THOMPSON:

Q. Dr. Parisian, I'm going to hand you a document

that's entitled curriculum vitae?

A. Yes, sir.

Q. Can you identify that for me please?

A. Yes, sir. It's my curriculum vitae.

Q. And look through it and see if it's up to date?

A. Yes, sir, and it's also my legal history, my legal testimony history is included here and that would probably be not up to date but the CV is.

Q. All right. I'd like to mark that as the next consecutive Plaintiff's Exhibit. Your Honor, I think we have a an ongoing question as to ultimate use of that exhibit but I did want go ahead and put it in at that time?

THE COURT: Let's mark that.

MR. THOMPSON: Why don't you hand it to me. Let me get it marked. 29. All right.

BY MR. THOMPSON:

Q. Now, let me hand you Plaintiff's Exhibit 29?

A. Thank you.

Q. Dr. Parisian just very briefly I want to go over your background and qualifications. What is your education?

A. I'm a physician an MD. That would be part of

my education.

Q. And where did you receive your medical degree from?

A. University of South Florida in Tampa.

Q. And where did you receive your PHD from?

A. I don't have a PHD. I have a bachelor degree and a master's degree from University of Central Florida.

Q. All right. Doctor after receiving your MD degree, were you licensed to practice medicine in any state?

A. Yes, sir.

Q. Where was that?

A. I practiced and licensed in many states. I originally when I got my MD I went and practiced in the State of South Carolina. And I practiced in North Carolina, South Carolina, California, Michigan. I currently have a license in Arizona and Virginia. So I have licenses in many states.

Q. Doctor, I want to look at your career after graduating from medical school and obtaining a medical license, if it's not delicate what year was that?

A. Oh, it was 1978 a long time ago.

BY MR. THOMPSON:

Q. And tell me your career after 1978?

A. My career is going to sound like I've been many places, but my husband also is a physician so we were trying to put two careers together. After I graduated medical school, I did a flexible internship in Greenville, South Carolina, which is basically general doctor taking care of all kinds of patients. Then I went to North Carolina and was a healthcare doctor, a family practitioner, general practitioner type doctor with the health departments. And after that I worked in an emergency room. I was president of a company called mountain emergencies in Durham, North Carolina. Then I went back to do training in pathology. So I'm board certified in anatomic and clinical pathology. So there's been periods of time when I have been doing general practice, and periods of time when I've been doing pathology. Eventually and the reason I'm sitting here today is because I went to work for the FDA.

Q. In your tenure at FDA, did you have opportunity to consider applications or submissions from corporate sponsors of new medications or devices?

A. Yes. That was what I did there I was looking

at both premarket, which would market applications and post market issues that would occur after products were marketed. So I was what they called a medical officer. I was in the center for devices radiological health, CDRH at the FDA that oversees medical devices. So I looked at pre-market applications post-market issues, yes, I did.

Q. Doctor, after leaving the FDA, did you continue in your career as a medical device evaluator or examiner?

A. Well, not after leaving the FDA, but I worked for industry to develop product applications to get cleared by, or approved by the FDA. So for the last 20-years -- I left the FDA in 1995. So for the last 20 years I've been involved with FDA related issues for manufacturers to get new products, and looking at applications.

Q. All right. Certainly here today, you're acting as an expert witness in a products liability trial. That's one of the things you do, as well; is that right?

A. Yes, sir.

Q. Now, Doctor, am I correct in saying that you are in the twilight years of your practice; is that

right?

A. I'm getting pretty gray yeah. Hopefully I'm going to be cutting this down, yes, sir hopefully it's not the twilight of my life.

Q. I didn't mean, if I said that I sure apologize. I didn't mean it?

A. No.

Q. But you are winding down your career?

THE WITNESS: I'm trying to. Yes, sir.

BY MR. THOMPSON:

Q. Doctor, in your experience, and in the things you've done, are you familiar with the organizing statutes and regulations which govern the submission of new product devices to the FDA?

A. Yes, sir. I was required at the FDA to learn about regulations, the food and drug and cosmetic act and what is required for a manufacturer. In fact, I actually had to teach it to other people at the FDA.

Q. Doctor, and does your training and your background give you expertise in reviewing and evaluating submissions by new drug or device applicants?

A. Yes, sir. And particularly as a medical officer, would review them as a physician.

Q. Dr. Parisian, in this case, which is what we're here for on behalf of Ms. Barba, as you know there are two devices that were implanted in Ms. Barba, a device called an Advantage Fit, and a Pinnacle pelvic floor product both manufactured by Boston Scientific. You're aware of that, aren't you?

A. Yes, sir.

Q. And in your review, did you review the various submission documents both for the Advantage Fit and for the Pinnacle?

A. Yes, sir.

Q. And have you -- did you review associated documents and associated information that gives you insight to and allows you to analyze those submissions?

A. Yes, sir.

Q. Doctor, I want to talk just for a minute about the 510k process at the FDA. First question: Does a clearance letter issued by the FDA to a 510k submitter, does a clearance letter mean that the FDA approves of the device?

A. No.

Q. What does it mean?

A. It means it clears the device to begin

marketing. It means that the company has submitted an application to the FDA that has supported, that they are substantially equivalent just like somebody else that's already being marketed for the same intended uses. And so that there has been a product already marketed for that intended use, is used by the FDA then to look at the next product and say well, this is just like that.

There aren't new issues of safety and effectiveness, so you can begin marketing. 510k are submitted when products haven't even been made yet. So the company is saying we're making this product and it's going to be just like the other guy's that's already been marketed for the same use.

Q. Is there any requirement that the product be a better product than anything on the market?

A. It has to be at least equal. It can't worse, it can't be inferior, it can be better. The FDA is not going to prevent something from being better or it cannot be worse or new risks that haven't been addressed by the company.

Q. When the submission is made by an applicant under a 510k, does the FDA test that product?

A. No. It's a paper application. When I first

went to the FDA, I'm going to see devices. So you're looking at paper. It's basically a paper document that the company tells you this is how this is going to perform, this is the type of product it's going to be. So you're looking at only the paper. There's no clinical trials or testing done by the FDA.

Q. All right. Now, with regard to the submission, what information, or what data is relied upon by the FDA in evaluating that submission?

A. It's all the data. In terms of the company has to say that they are being truthful and accurate and giving everything that the FDA needs to put this product on the market. So the FDA is relying on the value of the document and the information that's in it.

Q. Is there any requirement under the regulations that the company disclose material facts known to it with regard to safety and efficacy?

A. Yes. The regulation for 510k, 21 CFR 807 provides manufacturer provide that information, plus the manufacturer has to sign a statement called a truthful and accurate statement saying they're providing all the material facts in this document that the FDA needs to have to make the determination whether a product can

start being marketed.

Q. And does the clearance by the FDA, under a 510k submission process, study all the obligations of a medical device company to provide a safe and effective product to the physicians and the to the public?

A. Can you repeat that?

Q. Does the clearance meant that the FDA that a company has satisfied all its obligations to provide a safe and effective product to physicians and the public?

A. No. All it means is that they have satisfactorily put in an application that allows them to be able to market it. There's a lot of things that the FDA doesn't look at when they look at the application. One would be manufacturing documents, can the company actually make that product? They don't look at the labeling for a 510k, that's the responsibility of the manufacturer, the prescription labeling. So no, it's just a clearance that you as a manufacturer can start marketing the product, but you have to, as a manufacturer, make sure your product that you sell meets a lot of other requirements for manufacturers to sell a product in other states. So it's just a door that allows you to start marketing something. The life of

the product the FDA is not looking at, it's just okay you said you want to market this, okay you can start. You as a manufacturer have all these other duties.

Q. Does anything in a 510k clearance have anything to say about the design, or the installation, or the use the cleared product?

A. Well, it can, if the company provided that information. But the FDA is not looking at those things are well talking about this particular 510k?

Q. Yes, ma'am, I'm talking about the Advantage or the Pinnacle?

A. No, not in terms of the Advantage that was not described in terms of clinical risks for the patient that wasn't described, and the design actually would be under something different than the 510k, it's under 21 CFR 820 under good manufacturing process. So no, it didn't have that information.

Q. Does anything in a 510k clearance relieve Boston Scientific of its obligation to Ms. Barba, for example, to supply a safe and efficacious and nondefective product for her?

A. No, no. It's the 510k clearance is a prohibited act for any manufacturer, 21 USC 331, for a

manufacturer to sell a product in the United States that's not safe and effective. It doesn't matter how it even got on the market, you can't sell a product like that. Whether it's a food, whether it's a drug, whether it's a device.

So the 510k is just to let you market something. But the Act requires that you sell a safe and effective product for patients that are adequately labeled. That's the company's job.

Q. Does a 510k clearance satisfy the obligation of a company to design and make a safe nondefective product?

A. No.

Q. Who exactly is the examiner on a 510k submission for the FDA?

A. The typical 510k examiner and the ones that were involved in these 510ks are usually engineers, chemists, they are not doctors. So therefore the expert in the product is the company, not the FDA.

(Pause.)

MR. THOMPSON: Your Honor, may I approach the witness.

THE COURT: Certainly.

MR. THOMPSON: I'm going to go ahead and mark as Plaintiff's Exhibit 30 a 510k submission for the advantage.

THE WITNESS: Okay.

BY MR. THOMPSON:

Q. I'm also going to put in front of you at the same time Plaintiff's Exhibit 31, which is a 510k for the Pinnacle product?

A. Okay. One has a clip and one doesn't.

Q. Be careful with the one with no clip. We'll get you a clip at the next break.

A. Or rubber band.

Q. Or let's be specific about these two. Do you know who was the reviewer, or who signed off on the clearance letters?

A. The clearance letter for the Advantage was signed off by Mariam Provost, I know Mariam. She's a chemical engineer. The other one was signed off there's been various letters but eventually Mark Melberson who is director of that division and he's also an engineer.

Q. Is either one of them a medical doctor?

A. No.

Q. Dr. Parisian, what is an abbreviated 510k

clearance?

A. An abbreviated 510k was alternative type of 510k submission that was supposed to cut down the review time for the FDA reviewers, to try to streamline the process so the FDA reviewers didn't have to use as much time. It was based on certain changes, in terms of the requirements for manufacturers that manufacturers just provided saying that we met certain guidances, and the review is abbreviated, that's why it's called it an abbreviated 510k.

Q. Is there a time limitation on the FDA for considering a 510k submission?

A. For a traditional 510k is a mandatory 90 days. FDA tries to get through this type of an application in 90 days to decide whether you're going to clear it or not. There's no significant difference for a abbreviated, it's theoretical it's going to take less time, but 90 days is the working time that the reviewer has to get the application done by.

Q. Let's go to page 47 of the Advantage 510k submission. Michael, if you could post that for us so we can have a look at it. We need to blow that up a little bit so we can see it a little bit better. Little

bit more than that. All right.

Doctor, is this -- this is a document that is a flow sheet for the process by which a 510k submission is performed by the examiner; is that right?

A. Correct. A flow sheet would kind of reflect the engineering concept of the FDA, flow sheet. So this is traditional flow sheet that FDA reviewers have to use in order to determine whether to clear something as a 510k, or to ask for additional information, or not to clear it. So this is the process. Every 510k has one of these sheets in the chart. Manufacturers usually provide them, tell the FDA what they think the flow should be. So this is key to the FDA mindset.

Q. All right. Now, Doctor, this is the Advantage 510k submission. And it's dated in 2002; is that right?

A. Yes, sir.

Q. Is there a 510k for the Advantage Fit?

A. No.

Q. Why not?

A. The company made a determination that they didn't need a new 510k for the Advantage Fit.

Q. So from the time that this 510k -- do we know if it was an abbreviated 510k for the Advantage?

A. It originally was yes, sir.

Q. Do we know from 2002, until Ms. Barba in May of 2009 was there any submission with regard to the Advantage or Advantage Fit with regard to clinical information about the Advantage?

A. No.

Q. Now, I've circled, if you noticed I can actually make a mark on this. I've circled the vertical line and I want to go through this just briefly it says the name of this graph is "substantial equivalence." We've already talked about substantial equivalence. That means that -- well, don't worry what I mean. What does it mean?

A. It means that you are the same intended use as some product that's already on the market and you don't raise any new issues of safety and effectiveness that haven't been addressed. So you're substantially equivalent, just like the other guy that's already being marketed. So because you're just like the prior product you can claim all their history of use as support that you should be marketed.

So the opposite in terms of marketing, you're like be everybody else. There's no reason I'm

different. That's what they're trying to say to the FDA in terms of getting clearance. That's the key.

Q. Let's go to the top of this, it says new devices compared to marketed device. That's what you just said?

A. Right. The marketed device would be predicate device the word the FDA would use. So that's the already being sold product.

Q. Do you remember the predicate devices for the Advantage mesh?

A. The Trelex mesh, which was made by Boston Scientific, which is a polypropylene mesh. Biosling. The suspend sling, and the TVT Ethicon TVT tape, which is used for stress urinary incontinence. So those were the predicates that were cited by the company, and they were cited on the cover sheet. So that's what FDA is told. Those are the marketed devices that this new product is like.

Q. Michael, let's go quickly to 34. Keep that one in abeyance and we'll come right back to it. Let's see 34.

A. Okay.

Q. That's what we're looking at?

-01:-04:-53 A. Yes, sir.

-01:-04:-39 MR. KEENAN: Touch the screen.

-01:-04:-35 BY MR. THOMPSON:

-01:-04:-34 Q. These are the predicate device for Advantage as

-01:-04:-32 appears if their submission; is that right?

-01:-04:-31 A. No. These are the predicate devices that's on

-01:-04:-28 this table. When you look at their submission, these

-01:-04:-25 are not all referenced to the FDA, only the ones that I

-01:-04:-21 said, but these are the ones that are on a table. You

-01:-04:-18 have to have a table like this, so they added more

-01:-04:-15 predicates on the table.

-01:-04:-14 Q. All right. So we're looking, there is a Trelex

-01:-04:-10 that we talked about?

-01:-04:-08 A. Right that's Boston Scientific's mesh.

-01:-04:-06 Q. There's something called Insling which is

-01:-04:-01 actually a polyester; is that right?

-01:-03:-58 A. Yes, sir.

-01:-03:-58 Q. Then there's the TVT?

-01:-03:-56 A. Right here.

-01:-03:-54 Q. There's something called a Suspend, which is a

-01:-03:-50 polyether urea urethane elastomer?

-01:-03:-44 A. Right, so it's not polypropylene.

-01:-03:-42 Q. Then there's something called the IVS tunneler?

A. Which is polypropylene.

Q. And the Biosling bioabsorbable polymer sling which is a bioabsorbable polyester?

A. Correct.

Q. Then that looks like the Spark and the Uretex?

A. Right.

Q. So what they've done is they've pulled out other mesh types that are on the market to be look at?

A. Right, but they didn't discuss all those in their 510k, they only discussed the TVT and the Biosling and the Suspend and the Trelex. There's other ones here, but they are not all discussed.

Q. In fact, there's some problems with these other products, isn't there?

A. Yes.

Q. There are problems that arose and called the suspension of those sales; right?

A. Yes.

Q. Let's look at the Trelex mesh. Was that a mesh that was used for pelvic repairs in women's bodies?

A. No. And though give what the intended use is over that column. This is what it's cleared for. This is what a manufacturer can market it for, the intended

use. That's what FDA has cleared it to be sold for. So that's the only clearance for Trelex mesh and its basically a general surgical mesh.

Q. For hernias and chest walls?

A. Right.

Q. But it's being cited as a predicate device for an Advantage which is going to be used in the women's pelvis?

A. Well, it's being cited as a predicate for a surgical mesh that's what the FDA is reviewing here. One of the indications would be for the pelvis.

Q. What you're saying is the Advantage was put to the FDA as the substantially equivalent of Trelex?

A. Right.

Q. That's what the examiner saw?

A. Right. It's a surgical mesh. The 510k was called in the application was called a modified Trelex mesh and the cover letter. So the Trelex is a surgical mesh which is already cleared. So that's a predicate.

Q. Let's go down to the TVT, one real quick. Now, that's TVT is actually a brand name; is that right?

A. Right. That's the Ethicon tension free vaginal tape.

Q. And it is also a polypropylene mesh; is that right?

A. Yes. And they didn't include the clearance for the TVT here, they have part of it, but they don't have the essential part of the TVT, which also includes the clearance of the components that's not listed here. If you looked at the approved indication for use the TVT is not written correctly in terms of the way it's actually cleared.

Q. One of the things about the TVT mesh is that it actually has predicate devices that support its clearance, as well?

A. Yes, right, it does.

Q. And one of the predicate devices for the TVT is what?

A. It's Protegen, which is Boston Scientific.

Q. What was the recent history of Protegen?

A. The company withdrew in 1999 from the market.

Q. The reason?

A. Because the be variability of performance, it wasn't living up to Boston Scientific's standards for a sling.

Q. So what we're seeing with the 510k process is

that you can have a predicate device that's a defective device, but once you get cleared, you're cleared?

A. You're clear.

Q. Is that right?

A. You're cleared.

MR. KEENAN: Your Honor, objection, leading.

THE COURT: Sustained.

BY MR. THOMPSON:

Q. Is there a requirement that a predicate device be looked back to with subsequent devices on 510ks?

A. No. Once you're cleared, you're cleared. You're on the market. There isn't a process for FDA to remove the clearance.

Q. Let's go back to the flow chart.

So we've got the new device as compared to a marketed device?

A. Right.

Q. We compare this to the Marlex and to the TVT, if we're talking about Advantage?

A. Trelex. Trelex and TVT. Yes, sir.

Q. And then the next question; does the new device have the same indication statements?

A. And that's why there's a composite of predicate

devices with different indication statements, because the indication statement that they are requesting is actually more like Biosling's intended use, not TVT.

Q. That's fine. That's my question. In fact, the Advantage indication statement is not quite the same as TVT, is it?

A. No, it's not.

Q. Why does not invoke a no, and push it out?

A. It's because they gave other predicates. Biosling has an intended use similar to what they are requesting.

Q. Biosling is made out of biologic material?

A. Yes, it's a different type of material. Yes, sir.

Q. So let's assume that the answer is yes. So it goes down to what's the next step?

A. The new device may have same intended use and may be substantially equivalent.

Q. And then the next one down?

A. Does the device have the same technological characteristics, design, materials etc. This would also bring in the clinical use, are there new issues in terms of how it's going to be used. That would be in

technology.

Q. The next one down would be what?

A. Are the descriptive characteristics precise enough to insure equivalence, that's for the FDA, has the application been precise enough so the reviewer can make a decision.

Q. Then the answer to that whole column is yes then you get down to approval, or not approval, clearance?

A. Clearance with a 510k right.

Q. Okay. Now, let's go back up. Let's talk a little bit about the Advantage. We talked about the ProteGen that the predicate for the TVT was a polyester product called ProteGen, correct?

A. It was a colligens injected polyester.

Q. And the device for which the TVT is used to the device that is approved to install a TVT is what?

A. Pardon?

Q. Is there an insertion device?

A. When the TVT application 510k came to the FDA, they actually had a clinical study to look at the devices that are used, the accessories to make sure you can actually install the tape into the woman's pelvis.

So the TVT, when you look at the clearance, it's not listed correctly on that one sheet. But it includes not as much the emphasis on the tape because the tape it was Prolene which was a mesh and had been used for years it was putting into the woman's pelvis the equipment, the accessories. So the TVT was different. It wasn't the focus of the TVT wasn't the mesh.

Q. Let's look at the Advantage, was there an inserter device for the Advantage?

A. There wasn't a kit. They basically told the FDA that the physician could use available tools. They didn't describe delivery system. There were things there may be delivery tools, there may not, they don't need to be reviewed they are Class I, they are exempt.

Q. If, in fact, there was an intention to use the Advantage as part of the kit and to include an inserter device, is it your opinion that that should have been included in the 510k submission?

A. Right. That should have been stated in the very first cover letter to the FDA. Instead of saying it was a surgical mesh, they should said it was a kit. There should have been discussion, there should have been photographs of the components what was going to be

used. There are no photographs. It's really getting cleared as a surgical mesh, and the predicates they're citing in the clearance is that it's a surgical mesh.

Q. Now, Dr. Parisian, we've actually heard testimony in this courtroom earlier about the differences between the Prolene mesh of the TVT and the Advantage mesh. Are you familiar the statement or description of the Boston Scientific mesh as being de-tanged?

A. Yes, sir.

Q. What is that?

A. That means that there was, according to the 510k, it was FDA was told it was thermal treatment right at the urethra for their mesh.

Q. And was there any description or disclosure to the FDA that the de- tanged Boston Scientific mesh was twice as stiff, or twice as stiff as the TVT Prolene mesh?

A. No discussion. Because that would have been significant. That would be the change in technological characteristics.

Q. You've anticipated my next question. On this flow chart, if the delivery system that had been

disclosed as part of the kit, and if the stiffness had been disclosed in its submission to the examiner, who is the chemical engineer, would this have entailed additional scrutiny by the FDA?

MR. KEENAN: Objection may we approach Your Honor.

THE COURT: Yes.

(The following sidebar conference was held.)

MR. KEENAN: Well, we're starting to see Dr. Parisian work her magic. She's going to speculate about what the FDA would or wouldn't have done with information and she's going to continue to opine that the FDA will have taken a certain course of action and this device rules product misleading the FDA and she never been cleared on the market etc., etc., etc., if Mr. Thompson's question was asking about what the FDA would do, can or would likely have done we're seeing her at her best, which is speculating about not talking about what happened, in fact, happened but talking about what she thinks would possibly happen had certain facts been disclosed in a different way.

MR. THOMPSON: Judge, I think it's clearly within her expertise and it's within the expertise of an

expert to say if there is a matrix that is used to make decision and if, in fact, there were be additional facts adduced would it have triggered a left turn on the matrix and required that activity by the FDA. We're not insulating. That's simply that's what additional information would cause in the examiner.

MR. KEENAN: If she wants to opine about what she would do when she worked, tell FDA how she would interpret it that's different, that's different, but her talking about what the FDA would have done is completely improper.

MR. THOMPSON: I will restate my question.

THE COURT: Very well.

(Sidebar conference concluded.)

BY MR. THOMPSON:

Q. Dr. Parisian, if the additional stiffness and if the delivery system had been disclosed within the body of the 510k submission, if you were the examiner what would you have done?

A. If I was the examiner, I'd ask for information about the potential risk of having something thickened right at the urethral support. So I would have asked for additional information, which is what the FDA can do

00:-50:-27 1 if there's a potential new issue of safety and
00:-50:-24 2 effectiveness, that allows the FDA then to ask for
00:-50:-21 3 additional information. Particularly, we know with the
00:-50:-17 4 TVT, when they were told about the equipment, the tools
00:-50:-13 5 that the FDA was then able to ask for data to support
00:-50:-06 6 that you could actually use it the way you were
00:-50:-05 7 intending to use it. Without that information the FDA
00:-50:-03 8 can't ask that. They're basing what they can do on what
00:-50:00 9 the company is telling them they are going to be
00:-49:-57 10 marketing.
00:-49:-56 11 Q. All right. Doctor, let me turn from the
00:-49:-52 12 Advantage -- and here again, let me sum up just one
00:-49:-49 13 time. We're talking about the Advantage 510k; is that
00:-49:-46 14 correct?
00:-49:-46 15 A. Yes, sir.
00:-49:-45 16 Q. We're not talking about the Advantage Fit sling
00:-49:-41 17 as we sit here, are we?
00:-49:-39 18 A. Right. Now, the FDA didn't have the Advantage
00:-49:-36 19 name all they had was modified Trelex. There wasn't any
00:-49:-31 20 name given to the FDA for what this mesh what is going
00:-49:-28 21 to be sold as. That's okay. It said to be determined
00:-49:-23 22 or the Trelex mesh modified Trelex mesh which is a
00:-49:-17 23 surgical mesh when they are looking at the 510k.

00:-49:-15 Q. Let's turn our attention to the Pinnacle 510k now. And I want to put that flow sheet back up again please, the same one we just had.

00:-48:-56 Now, between 2002 and 2007, was there any change in the way that the examiner was required to look at the 510k submission?

00:-48:-45 A. No. That flow chart that we looked at still applies, still applies today.

00:-48:-40 Q. So now we're back with a new flow sheet. In fact, having done that, let's go to page 444, please. This is going to be a little bit hard to read because it's light print. But can we blow this up so we can get -- there we go.

00:-47:-58 Dr. Parisian, what is this?

00:-47:-55 A. This is a 510k -- let's see I think -- this is for the Pinnacle 510k and I think this is the 510k clearance letter if we can move it up.

00:-47:-38 Q. No, ma'am, this is a submission letter, I'm sorry, I should have just said that?

00:-47:-33 A. Yes, sir. This is the submission letter to the FDA.

00:-47:-31 Q. I want to start out with, does this letter form a substantive part of the submission?

00:-47:-23 A. This is the first thing the reviewer looks at. So it really sets, after having been a reviewer, it sets what you are going to be looking at in terms of the application.

00:-47:-12 Q. Let's look, first of all, to the second paragraph. Read that for me?

00:-47:-08 A. The proposed mesh is manufactured by Proxy Medical and is identical in terms of mesh characteristics to their previously cleared mesh K 051245. Everything at FDA in terms of devices is set by that identifier number, K for 510k. The only difference between their previously cleared mesh and the BSC proposed mesh are --

00:-46:-37 Q. Let's go to the first bullet point?

00:-46:-35 A. The dimensional shape and size of the mesh, the predicate mesh is a rectangular sheet ten cm by 15 cm, that is cut to size by the physician. The physician would use scissors to cut what they want. The proposed mesh is offered in three configuration, anterior, posterior and total.

00:-46:-13 Q. Your Honor, may I approach the witness for a second?

00:-46:-10 THE COURT: Certainly, you may move freely

throughout the courtroom.

BY MR. THOMPSON:

Q. Dr. Parisian, I've actually tried my hand on drawn something, check behind me and tell me if that's a ten by 15-centimeter rectangle?

A. Yes, sir.

Q. All right. It's at least close enough for government work?

A. For government work it is, yes.

Q. Let's put this on here like this.

(Pause.)

BY MR. THOMPSON:

Q. Let's get this Pinnacle device. Doctor, help me out. Put that in there. Spread that out for me?

A. Yes, sir.

Q. Let's show this to the jury. Doctor, is there anywhere in the world you could take a 10 by 15 centimeter rectangle or square Proxy Polyform mesh and cut a Pinnacle device out of it?

A. No.

Q. All right. As a matter of fact, you and I yesterday I showed you if well actually go to the diagram in the back, it would take a 27 by 21-centimeter

square, or rectangle to be able to cut that out of; is that right?

A. Yes, sir.

Q. Here let me -- everybody okay with that?

So would you use the term identical to describe the new use with the old approved use?

A. No.

Q. Would you believe that the Pinnacle intended use is the same as the Polyform intended use?

A. No.

Q. And would you say that the opening, the size of the device is the same?

A. No. And also you've increased the exposure of the woman to more mesh. So that was a new issue of safety and effectiveness.

Q. Doctor, let's look into the body of the 510k submission. Let's put up 465, Michael.

That is actually included in the 510k submission?

A. Yes, sir.

Q. Now, is there any comment by the examiner on this MSDS, within the Pinnacle clearance process?

A. Not in the clinical.

Q. The following year in 2008, when the Pinnacle two or the uphold is being submitted to the FDA, the examiner does talk about the MSDS; is that right?

A. Yes, sir.

Q. We'll talk about that in a minute, but with regard to Pinnacle submission, the examiner makes no comment on this; correct?

A. Correct.

Q. And Boston Scientific makes no disclosure that the MSDS for Marlex, in fact, contained a prohibition on impermanent implantation in persons; is that right?

MR. KEENAN: Objection, leading.

THE COURT: Can you rephrase?

BY MR. THOMPSON:

Q. Does Boston Scientific make any reference to any restrictions or prohibitions placed on this product by the component manufacturer?

A. No.

Q. Let's look at the Capio tool. And here again, we're talking about the insertion tool (indicating).

Dr. Parisian, this is the Capio instrument; is that right?

A. Yes, sir.

00:-40:-36 Q. Now, Doctor, this is described by the Boston
00:-40:-31 Scientific as a needle holder; is that right?
00:-40:-29 A. Yes, sir.
00:-40:-29 Q. If I looked to the 510k submission, the very
00:-40:-15 beginning there is a requirement that the submission,
00:-40:-11 the submitting party provide a listing of all 510k
00:-39:-59 submissions that have been put in with regard to any
00:-39:-53 item in the proposed device. Is that right?
00:-39:-48 A. That are relevant to that 510k, yes.
00:-39:-46 Q. Let's look at that real quickly. Let's look at
00:-39:-30 437. Is this the page?
00:-39:-25 A. I believe so. Let me see. It's hard to -- I
00:-39:-17 think it is right above where you can't read it.
00:-39:-05 (Pause.)
00:-38:-58 BY MR. THOMPSON:
00:-38:-57 Q. Doctor, what are the two that they refer to --
00:-38:-52 move it down. What are the two 510ks that Boston
00:-38:-44 Scientific referred the examiner to?
00:-38:-42 A. The Polyform predicate, which was the one that
00:-38:-36 was already cleared by Proxy.
00:-38:-33 Q. That's the identical product?
00:-38:-31 A. Right, that's the KO 51243. So the FDA knows
00:-38:-25 same mesh is being used for this product. Then the next

one they have is the Prolift, that's the Ethicon 510k which is pelvic floor repair mesh.

Q. Is there any 510k disclosure for the Capio tool?

A. No.

Q. Is there any way for this examiner, based on this filing, to know that the Capio has been the subject of multiple 510k filings before this?

A. No.

Q. Are you aware that in, I believe, 2002, Boston Scientific went to the FDA and got the Capio tool reclassified as a Class I device as a needle holder. Are you familiar with that?

A. Well, we know there's a 510k. I'm not sure if it's exactly the Capio device, there's a 510k that's cleared as a needle holder.

Q. In any event, the 510k -- the device that's included in the Pinnacle kit is the subject of an earlier 510k submission; is that right?

A. Three, three earlier ones. Yes, sir.

Q. Was the proposed use for the Capio device open surgery supported by an endoscope?

A. Yes, it was an endoscope accessory.

Q. What is an endoscope?

A. An endoscope would be considered a big long black tube that's got a camera at the end so you can see what's going on where you're working.

Q. Is the approved use for the Capio that it would be used in abdominal or -- well, used in surgery where the device could be visually controlled?

A. Right. There would be some visibility.

Q. Are you aware that the Pinnacle device contemplated that the Capio would be used blindly by the inserting physician?

A. Yes, without a trocar. Yes, sir.

Q. And the inserting physician would be expected to find the appropriate place of attachment using anatomical landmarks; is that correct?

A. Yes, sir.

Q. There's not a little camera on the end of the Capio. We just looked at it?

A. That is correct.

Q. Is this a different use for the Capio tool?

A. Then when it was originally cleared for? Yes, sirs.

Q. Is this the first time in the history of the

world that the Capio is being contemplated to use in a woman's pelvis for insertion of a pelvic floor device?

A. Yes, sir.

Q. Now, is the point of insertion of the Capio device, the point of attachment, is that the sacrospinous ligament?

A. Yes, sir.

Q. Is the attachment of an anterior Pinnacle and, here again, you're going to have to bare with me, anterior means front?

A. Right.

Q. Are you familiar with any other device that uses the sacrospinous ligament to attach any sort of hard-point attachment of a device to the sacrospinous ligament from an anterior approach?

A. Not from an anterior.

Q. Is this, in fact, a new and novel use of the Capio?

A. Yes. And it also becomes new and novel based on their marketing, too, what their claims are what it will do. That wasn't what was cleared in terms of a general surgical instrument.

Q. Were there any animal, or clinical testing

provided to the FDA examiner for this 510k proposal?

A. For the Pinnacle?

Q. Yes, ma'am.

A. No, sir.

Q. Okay. Are there new and unknown risks entailed with the method of insertion of the Pinnacle?

A. Yes.

Q. Is the technique for insertion of the Pinnacle novel and unique?

A. In terms of the risks, yes, sir.

Q. Let's go back to the flow chart.

Dr. Parisian, if you were the examiner and you became aware of the prior classification and the prior use of the Capio, you became aware of the intended use of the Capio, the intended attachment points, would you view that as new or novel issues?

A. Yes. They would raise new issues with safety and effectiveness. So that would then open up FDA to ask for additional information.

Q. Let's guide our way down. If you are the examiner, you get the new device --

A. Remember, I would be clinical. The person who is the examiner is an engineer. And so they're relying

on the company to have provided them the safety issues. So they don't have the luxury of having knowledge of this anatomy and the potential risks. That's why they look to the company to provide that information to them.

Q. Where we would make a left turn would be here (indicating)?

A. Right.

Q. Now, in fact, the Pinnacle submission the examiner did have some questions, didn't he?

A. Yes, he did.

Q. And one of the questions he had involved the indications for use?

A. Right.

Q. Is that right? Can we go to 605.

What is -- describe for me what we're looking at?

A. The FDA sends out what they call a request for additional information. So they're allowed to ask some questions because they can't complete their review. So they're asking Boston Scientific for some information about what they're looking at in terms of marketing application.

Q. Now --

A. What I mean, specifically question three that would be the FDA's question and bottom would be the Boston Scientific's response. And I believe -- I don't know if this was sent, or it's a draft letter.

Q. Well, let's just -- whatever it is it's Boston Scientific's responses. The FDA says that the application suggests proposed and predicate devices have the same indications, but we note that your proposed device has an additional sentence, this includes but is not limited to enterocele, rectocele, and cystocele, and vaginal vault prolapse repair?

A. Yes.

Q. And the FDA asked to provide information about that use, those uses; right?

A. Right. They're saying please provide information that identifies the legally marketed device indicated for and those indications. That means you can't 510k it unless there's a device that has that similar indication. You can ask for additional information, you can consider other ways to get this product approved, but you can't use the 510k if you don't have a predicate.

Q. Now, in fact, the anticipated use of the

00:-29:-51 Pinnacle was to repair enteroceles, rectoceles,
00:-29:-44 cystoceles, and vaginal vault prolapse repair; isn't
00:-29:-40 that right?
00:-29:-40 A. In terms of the marketing. Yes, sir.
00:-29:-39 Q. In terms of Ms. Barba?
00:-29:-37 A. Yes.
00:-29:-37 Q. The intended use of the Pinnacle was to repair
00:-29:-34 a cystocele?
00:-29:-33 A. Correct. And there is no surgical mesh that's
00:-29:-30 approved or cleared for that indication.
00:-29:-27 Q. Well, when we get down to BSC response is what?
00:-29:-21 A. They delete the indication. They don't tell
00:-29:-14 the FDA that they are planning to market it for it, but
00:-29:-11 we're going to delete the indication.
00:-29:-10 Q. Did they, in fact, market it for exactly that?
00:-29:-07 A. Yes.
00:-29:-07 Q. Okay. Now, the other devices that they
00:-29:-03 referred to are what?
00:-29:-01 A. What do you mean "the other devices," the
00:-28:-57 predicates?
00:-28:-56 Q. Let me ask you a couple more questions.
00:-28:-51 A. Well, the first submission was the Ethicon
00:-28:-44 prolene soft, the Proxy Polyform.

00:-28:-39 Q. Let's go to Bates 602, please.

00:-28:-28 Do you recall, this is, I think, this is continuing the FDA examiner's questions about the Pinnacle; correct?

00:-28:-13 A. Right.

00:-28:-13 Q. Read me the question?

00:-28:-07 A. Recently CDRH has received several hundred complaints including five deaths, related to surgical meshes used in gynecological surgery. These reports included patients experiencing adverse events such as mesh erosion, and extrusion, infection, abscess formation, sepsis, as well as organ and vessel perforations, post-operative bleeding, hematoma and incontinence. Many of these patients required additional surgery to remove a portion of the mesh, adhesions, provide antibiotic therapy, blood transfusions and/or repair injuries related to the initial surgery.

00:-27:-19 Because you proposed a device with a novel design in which physicians may not directly observe device placement, please provide information that addresses the following concerns.

00:-27:-05 Q. Keep going.

00:-27:-04 A. Please provide information that support your
00:-26:-51 hypothesis that the Pinnacle pelvic floor repair kit
00:-26:-47 will be a safe and effective active device that avoids
00:-26:-44 the adverse events cited above. Given the novel design
00:-26:-40 of your product, the blinded manner of its implantation,
00:-26:-36 the significance of the adverse events cited above, and
00:-26:-31 the possibility that animal models may not accurately
00:-26:-27 reflect the mechanical forces and stresses in humans
00:-26:-23 implanted with your device, such safety and
00:-26:-20 effectiveness information may include a clinical
00:-26:-17 evaluation of your device.
00:-26:-15 If you would like guidance on the design of
00:-26:-13 such a study, or submission of an investigational device
00:-26:-06 exempt application, please contact Colin Pollard chief
00:-26:-01 of the obstetrics and gynecology devices branch at and
00:-25:-58 that's his e-mail.
00:-25:-57 Q. Let's go down to their response. This is
00:-25:-53 Boston Scientific's response. Okay. What's the first
00:-25:-49 thing they say?
00:-25:-48 A. As discussed previously, in response to
00:-25:-46 question one, the proposed shapes and sizes of the
00:-25:-42 Pinnacle pelvic floor repair kits are not unique and not
00:-25:-38 of novel design. Currently available rectangular

meshes, such as Polyform are cut to size by the physicians prior to placement, and often the physicians may place more than one mesh per patient. Additionally, there are several preshaped products commercially available for the treatment of pelvic organ prolapse that have similar dimensions, shape and size, as the Pinnacle mesh configurations. The placement of the Pinnacle pelvic floor repair kits uses the same anatomical landmarks as the predicate devices.

Q. Scroll that up a little bit for me to the end. The next paragraph, please?

A. Also, as detailed in the response to question one, all of the predicate devices' meshes are delivered to the anatomy using trocar type device, those would be the things so you can see. The predicate device trocars are placed from outside the body, through an incision in the patient's skin, puncturing through bodily tissue, trans cutaneous. The trocar is advanced blindly in the direction of the desired anatomical landmark that is identified through palpation by the physician's fingers from within the vaginal incision. The physician aims and advances the trocar towards his or her finger to create the needed path for mesh delivery.

Q. Now, does the response from Boston Scientific recognize that their design is new and novel?

A. No.

Q. In fact, what do they say?

A. They're saying it's not. They're saying it's not unique and not novel.

Q. Do they volunteer to address the safety and efficacy concerns of the examiner?

A. No.

Q. Are they forthcoming with the examiner?

A. No.

Q. Now, let's go back to the flow chart. Let's look at 488, please.

As a result of the examiner's questions they actually followed an amended question for the Pinnacle; is that right?

A. Yes, an amended.

Q. They added a bunch the additional predicate devices; is that right?

A. Yes, sir.

Q. In fact they added every major manufacturer of every major pelvic product; is that right?

A. Yes, sir.

Q. Is there any indication that you have that Boston Scientific sought to have these devices not treated on their own device, but to have them treated as a member of an entire class of devices?

A. Yes, sir.

Q. I forgot to ask you a summary question. Doctor, based on the information with regard to the Capio, with regard to the attachment of the anterior to the sacrospinous ligaments, with regard to the size of the coverage of the shape, based on those factors, if you were the examiner, would you have viewed this as a new and novel design that required further inquiry?

A. I would have. I would have asked for additional information. The FDA was suggesting that when they recommended getting clinical data.

Q. Look at this letter dated November 6, 2007. And that is -- it's to Dr. Charles Durfor; is that right?

A. Yes, sir.

Q. From who?

A. From Boston Scientific.

Q. Scroll down. Let's look at the third paragraph; "as discussed," read that had for me?

A. As discussed during our telephone call, we realized that FDA is evolving its direction on labeling requirements for surgical meshes used in pelvic floor repair. We understand and appreciate FDA's desire to ensure that the physician and the patient are provided appropriate and current information. We believe that the intent of several of the recommended changes have been met. FDA was asking for a series of changes to the label.

Q. And let's go to the next paragraph. Read that for me?

A. Since we have not found language similar to these recommendations in the labeling of the predicate devices identified in 510k, not in FDA's guidance document for surgical meshes, we are perplexed by FDA's approach to have these modifications implemented only in this submission. We strongly believe that it would be more appropriate and effective for all parties involved in the manufacture and use of surgical meshes for FDA to request that these labeling changes be embraced by the entire surgical mesh industry, not just pelvic, but all surgical mesh. We believe that having similar products in the marketplace with different FDA mandated labeling

will cause confusion among physicians and patients.

Q. All right. Now, let me understand what we're saying here. The FDA is evolving its position; is that right?

A. Yes, sir.

Q. And we've seen the examiner talk about reports of serious adverse events; is that right?

A. Right, evolution, that would be post marked issues, ODE people looking alternative these applications are premarket. So somehow they become aware of these products being used and the post market part of FDA has brought this to their attention. So it's helping to evolve as what's being described here.

Q. You don't what May 12, 2009, is do you?

A. That's Mrs. Barba's surgery.

Q. You do know that. All right May 12, 2009. As of November of 2007, did Boston Scientific embrace the FDA's concern for safety and efficacy of these pelvic floor products and seek additional information to provide safety to Ms. Barba?

A. No.

Q. In fact, what did they propose?

A. They wanted it to be all surgical meshes had to

have the same types of information.

Q. Now, surgical mesh is different than surgical mesh implanted into the pelvic region by pelvic floor kits?

A. That's correct.

Q. How long does it take to get a class-wide label change?

A. It can take at least a year, closer to two years because you're going to have to get all kind of comments periods. FDA has certain requirements in terms of trying to get class label. If they can negotiate it voluntarily, that's much better than having to go through the process of taking an entire class, going through the type of class or type of product change.

Q. The FDA regulations, the prevailing statutes require a medical device company that becomes aware of a safety issue to communicate that; is that right?

A. Yes.

Q. Do they have to wait on the FDA?

A. No. No, the manufacturer can immediately update their labeling, their sales reps. They're required to update their prescription label. They can

00:-17:-16 communicate at all times with doctors and through their
00:-17:-13 only sales reps and that's usually what they do.
00:-17:-10 THE COURT: We need to take a break at some
00:-17:-07 point.
00:-17:-07 MR. THOMPSON: Your Honor, this is fine. I've
00:-17:-04 probably got 20 more minutes on direct.
00:-17:00 THE COURT: Let's take a break.
00:-16:-55 (The jury left the courtroom at 11:38 a.m.)
00:-16:-27 THE COURT: Dr. Parisian, you've probably been
00:-16:-25 told you cannot discuss your testimony with anyone when
00:-16:-21 you're on a break.
00:-16:-20 THE WITNESS: Yes, Your Honor.
00:-16:-15 (A short recess was taken.)
00:-02:-21 THE COURT: Bring in the jury.
00:-01:-39 (Pause.)
00:-01:-38 (The jury entered the courtroom at 11:54 a.m.)
00:-01:-02 MR. THOMPSON: May it please the Court?
00:00:-58 BY MR. THOMPSON:
00:00:-57 Q. Dr. Parisian, let me get back to what we were
00:00:-54 talking about. The FDA issued a clearance letter to
00:00:-49 Boston Scientific for the Pinnacle?
00:00:-47 A. Yes, sir.
00:00:-46 Q. And did that clearance letter approve the

00:00:-43 Pinnacle?

00:00:-42 A. No.

00:00:-42 Q. Did it relieve Boston Scientific of any obligation it had to comply with and conform to all regulations?

00:00:-32 A. No, it did not.

00:00:-31 Q. Did it relieve Boston Scientific of any obligation to provide a safe and nondefective product to the consuming public?

00:00:-21 A. No, it did not.

00:00:-20 Q. All of those obligations remain with Boston Scientific; right?

00:00:-15 A. Correct.

00:00:-15 Q. Now, post clearance, is there a branch of FDA that follows and tracks the public health?

00:00:-04 A. Yes.

00:00:-03 Q. Now, in fact, we saw with the FDA examiner saying we've had several hundred reports?

00:00:03 A. Yes.

00:00:03 Q. What would be the source of those reports?

00:00:05 A. That would be the post-market branch which would be office of surveillance and biometrics more compliance arm they're the ones that look at that type

of stuff, ODE wouldn't.

Q. All right. My efficient staff has picked it up before I'm aware. Is this a copy of the clearance letter?

A. Yes.

Q. And that's included within the package of the 510k that we've already gotten. So we don't need to mark it separately. But is this a clearance letter?

A. Yes, sir. This allows the company to begin marketing the product.

Q. Within the body of the letter, is there a statement that sums up what we were just talking about with regard to the company's continuing obligations?

A. Yes. That's the third paragraph.

Q. Let's highlight the third paragraph. All right. Read that for me?

A. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirement, that's a food and drug and cosmetic act,

including but not limited to registration and listing which is 21 CFR part 807, labeling means they have to create a label. 21 CFR part 801, good manufacturing practice requirements as set forth in the quality systems QS regulation 21 CFR part 820. That's the product in terms of manufacturing where a manufacturer has to do in terms of marketing a product and selling it and making it, and if applicable, it's not here, it's not an electronic device.

So these are the requirements. In the very first paragraph it says we've shown that you're substantially equivalent, that's what you're cleared for. But you describe something, you filled in an application now you can start marketing. Now is the real life of the product is once it gets cleared the manufacturer now has to make sure the product is safe and effective when it's used in patients.

Q. Let's go to July of 2008. This is after the Pinnacle has been cleared. Is there a device that Boston Scientific has submitted called Pinnacle II?

A. Yes. It's the modified Pinnacle, yes, sir.

Q. And, in fact, were there examiner questions with regard to the modified Pinnacle?

00:03:02 A. Yes.
00:03:02 Q. Would you pull that up for me.
00:03:22 (Pause.)
00:03:22 BY MR. THOMPSON:
00:03:31 Q. Let's highlight what the FDA examiner's
00:03:34 question is.
00:03:44 Dr. Parisian, can you identify this document?
00:03:46 A. This is Boston Scientific's responses for the
00:03:51 FDA's questions for additional information for the 510k
00:03:55 which marketed the Uphold device. I'm not sure if this
00:04:01 is the draft there's draft ones. I'm not sure if this
00:04:05 is actual submitted once.
00:04:06 Q. There's a thing that K 081048?
00:04:12 A. That's 510k model for modified Pinnacle II
00:04:16 which is eventually sold for the Uphold.
00:04:19 MR. THOMPSON: Your Honor, I'm not sure if this
00:04:22 group was previously offered in this action but we would
00:04:27 like to offer it.
00:04:29 MR. KEENAN: No objection.
00:04:33 MR. THOMPSON: Certainly I want to offer into
00:04:36 the evidence the two 510ks that were previously
00:04:40 identified.
00:04:40 MR. KEENAN: No objection.

00:04:41 THE COURT: Very well.

00:04:42 BY MR. THOMPSON:

00:04:49 Q. Dr. Parisian, I'm going to hand you Plaintiff's
00:04:53 Exhibit 32, which is hard copy version of what you're
00:04:55 looking at on the screen, okay?

00:04:57 A. Yes, sir.

00:04:58 Q. What is the examiner asking about?

00:05:02 A. This particular case question is about the
00:05:05 Capio. The Capio's suture capturing device. Saying
00:05:11 that there's a large number of adverse events reported
00:05:14 to the FDA regarding tip breakage of the Capio suture
00:05:19 capturing device. Please include instructions on how to
00:05:23 manage such an adverse event during surgery.

00:05:26 Q. And their response is what?

00:05:29 A. The company says we disagree that the number of
00:05:32 adverse events reported to the FDA regarding tip
00:05:36 breakage of the Capio suture capturing device is large.
00:05:40 Our records indicate that there were only 7 MDRs for the
00:05:46 Capio suture capturing device to be packaged within the
00:05:50 pelvic floor repair kits from January 2006 through
00:05:54 May 2008. Over the this same period of time 53 thousand
00:06:00 five hundred Capio suture capturing devices were sold.
00:06:04 Therefore, the average MDR rate is 0.013 percent.

00:06:16 Q. All right. Dr. Parisian, I'm going to put on
00:06:25 the board something entitled the Field Assessment Plan,
00:06:28 which has already been put into evidence as Plaintiff's
00:06:31 Exhibit 18.
00:06:36 Let's turn to page 3 of 34. This is a field
00:06:49 assessment of the Pinnacle Anterior Apical PFR kit, do
00:06:57 you see that?
00:06:57 A. Yes, sir.
00:06:58 Q. It assesses the performance of the Pinnacle
00:07:01 Anterior Apical PFR critic from December '08 -- well,
00:07:08 January '08, through December '08; is that correct?
00:07:11 A. Yes, sir.
00:07:12 Q. And it uses a baseline failure rate of
00:07:16 6500 parts per million; is that right?
00:07:20 A. Yes, sir.
00:07:20 Q. Is that an FDA standard?
00:07:22 A. No.
00:07:23 Q. Is that an industry standard?
00:07:25 A. No.
00:07:26 Q. Is that an ISO standard?
00:07:29 A. No.
00:07:29 Q. Is that a ATSM standard?
00:07:35 A. No.

00:07:36 Q. Who made that standard?
00:07:37 A. Boston Scientific. They set that as their
00:07:41 acceptable limit for a number of reports.
00:07:44 Q. And what is the result of the -- before I ask
00:07:49 you that, do they actually have complaints for mesh
00:07:55 suture and Capio?
00:07:57 A. Yes.
00:07:58 Q. And then if you put those together, what is the
00:08:02 complaint rate for --
00:08:05 A. It's much higher than -- yeah, there you go,
00:08:09 complaint rate. So the Capio even exceeds the 65
00:08:14 hundred. But you can look at the mesh complaints and
00:08:17 suture complaints.
00:08:17 Q. If I turn the page to 434, in fact, the average
00:08:23 for the year is 38,250 parts per million?
00:08:27 A. Correct. So that's not acceptable in terms of
00:08:30 65 hundred.
00:08:30 Q. In fact, that's six times the maximum failure
00:08:35 rate or the maximum complication rate?
00:08:38 A. As set by Boston Scientific. Yes, sir.
00:08:40 Q. All right. So let's go back to their response
00:08:43 to the FDA.
00:09:01 It says, we disagree that the number of adverse

events reported to FDA regarding tip breakage of Capio suture capturing device is large. Our records indicated that there were only 7 MDRs for the Capio suture capturing device to be packaged within the pelvic floor repair kits from January 2006 to May 2008. First of all, what is an MDR.

A. That's a Medical Device Report, it's described in 21 CFR 803, and it's a mandatory report filed by industry, or it can be voluntary reports. It's in the FDA's database. It's what the FDA has received. It's not complaints that Boston Scientific has. It's what the FDA has managed to get in their database.

Q. So would we be justified in assuming that although the FDA did not ask for the number of MDRs, that's what Boston Scientific provided as their response to the FDA; is that right?

A. Yeah, the FDA has the MDRs and FDA is saying that it's a large number for the Capio. And the company is saying no, it's not in terms of the reply, and what the FDA is really asking is what is the company receiving for the Capio device because the FDA doesn't have the company's complaint file.

Q. If the field assessment plan is correct, did

00:10:31 the company have information exclusive to itself that
00:10:35 was not available to the FDA?
00:10:37 A. Yes.
00:10:37 Q. If in fact, the company is under an obligation
00:10:42 of being truthful and forthcoming, looking at these two
00:10:47 documents juxtaposed, were they satisfying that
00:10:50 obligation?
00:10:50 A. No, they weren't providing accurate reports to
00:10:55 the FDA.
00:10:55 Q. Now, in this same inquiry of July 17th, 2008,
00:11:04 did the FDA request information about the manufacturer
00:11:10 safety data sheet?
00:11:11 A. Yes.
00:11:11 Q. Now, this is not the Pinnacle request, is it?
00:11:15 A. No. This is later Uphold.
00:11:18 Q. This is a device that became known commercially
00:11:22 as the Uphold; is that right?
00:11:24 A. Yes.
00:11:24 Q. In that request it looks like the examiner
00:11:28 checked the Uphold more closely than he checked the
00:11:34 Pinnacle?
00:11:34 MR. KEENAN: Objection, Your Honor, can we
00:11:36 approach?

THE COURT: Yes.

MR. THOMPSON: Why don't I withdraw that question, if that's okay.

MR. KEENAN: Subject to the Court's previous instruction, yes.

MR. THOMPSON: All right.

BY MR. THOMPSON:

Q. Dr. Parisian was the MSDS, the Manufacturer Safety Data Sheet included in the Pinnacle 510k?

A. Yes.

Q. Was the Manufacturer Safety Data Sheet included in the Uphold or the modified Pinnacle?

A. Yes, same sheet.

Q. Did the examiner in the Pinnacle make any inquiry about the MSDS?

A. No.

Q. Did the examiner in the Uphold make any inquiry about the MSDS?

A. Yes, it did.

Q. In response to the question from the examiner, did Boston Scientific recite prior experience with the Marlex polypropylene resin?

A. Yes.

Q. And did they recite the study, the rabbit study that was conducted on the Advantage mesh?

A. Yes.

Q. Is, in fact, the Advantage mesh the same as the Polyform mesh?

A. The resin is, but there's difference in terms of the final production of the proxy mesh in terms of trying to make it softer, there's extra steps put into it.

Q. Did Boston Scientific conduct any additional testing on the Polyform mesh in response to the examiner's question about the MSDS sheet?

A. No.

Q. One final thing about the 510k for the Pinnacle. Let's go to page 464, please.

How about making that bigger. Appendix 9A MSDS for Marlex HGX 30001?

A. Yes, sir.

Q. In fact is that a truthful and correct statement?

A. No.

Q. Why not?

A. Because that's not the Marlex mesh. It was

Marlex HGX 0303-01. It's the same Marlex resin used in the Advantage and the same Marlex resin that was used for biocompatibility testing. So that's not the correct resin.

Q. So this is a paragraph and I believe later on in this document it's referred to as a Marlex HGX 300-01?

A. Yes, it doesn't exist, as far as I can find.

Q. And does this speak to the proof reading and care with which this document was assembled?

A. Yes, it's incorrect. It's a major error and it's continues -- but it's not just on this page, it's continuous for --

MR. KEENAN: Objection, Your Honor. Your Honor that's --

THE COURT: Right.

BY MR. THOMPSON:

Q. Doctor, did the FDA, not the part that's looking at clearance. We've talked about that probably more at length than anybody wants to hear about. I'm talking now about the surveillance part. Did there come a time when the FDA surveillance folks ascertained a public health risk from the surgical mesh that was used

in these pelvic products?

A. Yes.

Q. And did they, in fact, advise the manufacturers that they intended to issue a public health notice?

A. Yes.

Q. And did they receive a response from industry prior to the public health notice?

A. Industry and physicians. It was -- yes.

Q. Dr. Parisian, I want to hand you Plaintiff's Exhibit 33, please?

MR. KEENAN: Mr. Thompson, can we approach briefly.

MR. THOMPSON: Please.

(The following sidebar conference was held.)

MR. KEENAN: This is not an objection, per se. But it is a request for original, actually she used this document because this is not a Boston Scientific document, it's not an industry document. Boston Scientific isn't anywhere on this but I will guarantee you see it's by physicians Pelvic Health Coalition. She's going to jump from this to Boston Scientific. This is Dennis miller, who is a physician who happened to be for Pinnacle. He's not an employee, he is a

consultant for Boston Scientific. Boston Scientific is nowhere to be found on this cease, going to use this and talk about Boston Scientific and I'm going to be objecting like crazy. All I'm doing I'll let you lead but this is not a Boston Scientific document and it's an industry document, it's a physician document that if she speculates anything about this I'm going to be on my feet. Fair enough?

MR. THOMPSON: Sure.

THE COURT: Also while we're here I assume since there's been no objection everyone is comfortable with the fact that this witness knows the relative time period she's talking about?

MR. THOMPSON: Your Honor, we are abiding by your ruling.

THE COURT: I knew that you were. I wanted to make sure the witness new.

MR. THOMPSON: Yes, she's not going to volunteer any after 2009.

THE COURT: Very well.

(Sidebar conference concluded.)

BY MR. THOMPSON:

Q. Doctor, I've been will told by my competent

staff that I've given you a bum copy. Let me substitute Plaintiff's Exhibit 32 from that. This is a document from the Pelvic Health Coalition?

A. Yes, sir.

Q. You've had an opportunity to review that document; is that right?

A. Yes, sir.

Q. One of the executive board members is a Dennis Miller, MD. Do you see that?

A. Yes, sir.

Q. Are you aware that Dennis Miller is the inventor and patent holder for the Pinnacle?

A. Yes, sir.

Q. Are you aware that Dr. Miller is a consultant with Boston Scientific?

A. Yes, sir.

Q. Are you aware that Dr. Miller is in fact Boston Scientific's representative on the Pelvic Health Coalition?

A. Yes, sir.

MR. KEENAN: Objection, speculation.

THE COURT: Is that not accurate? Or it's based on the witness's knowledge.

MR. THOMPSON: Your Honor, she's reviewed documents that -- well, I'm talking too much in front of the jury but --

THE COURT: Try to lay a foundation for her knowledge on that issue.

MR. THOMPSON: Let me withdraw that question and we'll move on.

BY MR. THOMPSON:

Q. Doctor, is this a communication to the FDA?

A. Yes, sir.

Q. And is this a document that seeks to have the FDA not issue a public health notice regarding safety issues of pelvic mesh?

A. Yes.

Q. Now, if I could put up -- let me hand you Plaintiff's Exhibit 34. This is a document entitled FDA Medical Devices FDA, Public Health Notification Serious Complications Associated with Transvaginal Placement of Surgical Mesh and Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence?

A. Yes, sir.

Q. Can we figure out the date of this from the date of the document itself?

00:21:28 A. October 20, 2008.
00:21:29 Q. So if we look at the Pelvic Health Coalition
00:21:35 letter, that's this days before; correct?
00:21:38 A. Yes, sir.
00:21:38 Q. Doctor, this public health notice is advice
00:21:44 that the FDA has received over a thousand complaints of
00:21:49 serious injury; is that right?
00:21:51 A. Yes, sir.
00:21:52 Q. Is the MAUDE reporting system a voluntary
00:22:03 system?
00:22:03 A. Yes, sir. Well, not for industry it's
00:22:07 mandatory, for physicians and anyone else you can
00:22:10 report.
00:22:11 Q. Say for example Ms. Barba had a bad outcome
00:22:14 from a Pinnacle surgery, is Dr. Carlson under a mandate
00:22:18 to report that to the FDA?
00:22:21 A. No. He can. Same with Ms. Barba, she can.
00:22:25 Q. In your body of knowledge and within your
00:22:31 expertise as a regulatory expert, is there, in fact, a
00:22:35 rule of thumb as to the expected number of, or
00:22:40 percentage of serious injuries that actually get
00:22:43 reported?
00:22:43 A. Yes in terms of working with this you the FDA

would think of maybe one to 10 percent max is actually getting reported to the FDA. There's numbers to support that. If there's a delay involved like something that's implanted, you would think that your reporting is even less because people just don't associate with the product with the complaint. So FDA looks at reporting, when I was at the FDA looking at MDRs as just a tip of an iceberg. So they're saying there's a thousand -- which is a large number, the FDA is concerned about a thousand reports it has received in its database.

Q. Let's actually scroll down a little bit and put up the nature of the problem, if you could highlight that. Of course, everybody in the regulatory industry knows about this under reporting; is that right?

A. Yes, Congress has been trying to come up with alternative types reporting mechanisms.

Q. If they are reporting on a thousand complaints there's expectation that the actual number of injuries is greatly higher than that; isn't that right?

A. Yes. By the FDA. Yes, sir.

Q. I'm not sure we need to read this exactly. It's now in evidence. But it does report to over the last three years FDA has received over a thousand

reports from nine surgical mesh manufacturers from complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement; right?

A. Yes, sir.

Q. And that's as of October 20, 2008?

A. Yes.

Q. Now, did the FDA continue to seek information regarding complications, and regarding the public safety issues involving these transvaginal replaced pelvic devices?

A. Yes.

Q. Ms. Barba's device was placed on May 12, 2009; correct?

A. Yes, sir.

Q. Are you aware of any communication from Boston Scientific to treating physicians alerting them of the complications that were being seen and were being reported by the FDA?

A. Not alerting them, no, sir.

Q. You've had an opportunity to look at the directions for use of the Pinnacle and the Advantage; is

that correct?

A. Yes, sir.

Q. Do you have any criticisms of the directions for use?

A. Yes.

Q. And what specifically do you think should be placed in those directions to make them more -- to satisfy your concerns?

A. Well, one of the issues is that when a product comes out it's to have a label that is updated with information that's about that product. And so the information has not been updated to include what the risk is for failure, or complications like revision surgery, difficulties with the product, reoccurrence of symptoms. That information has not been added by Boston Scientific for their product. It's a very generic kind of a label that doesn't specifically say what's occurring. There's nothing really alerting physicians about what is happening with Pinnacle as opposed to just a label.

And the DFU, they call it Directions For Use is one document but usually the sales people are updated to also tell the doctor what is the new information that's

now being added to the label. So it's not just the label, that's the label, but labeling is everything the company communities to a doctor, whether through doctor letters, through its sale reps, through patient brochures, that information is not being updated with what's occurring with Pinnacle.

Q. All right. Doctor, let me go back just one last time to the Pinnacle premarket notification. Let's go to 453.

Doctor, we've talked a little bit about how the FDA relies on the truthfulness and accuracy on the applicant who is submitting the request for premarket clearance; correct?

A. Yes.

Q. In fact, that's actually a page in every 510k; isn't that right?

A. It's required that this page be signed and present, otherwise the 510k won't be accepted. Though it is a requirement for the 510k. And it says as required by, and then it has 21 CFR 8097, so it's required.

Q. So Boston Scientific, through its representatives, certifies to the FDA that the

00:28:17 information contained is truthful and accurate. And I
00:28:22 guess I want to ask you one additional thing, and that
00:28:25 no material information has been withheld; is that
00:28:28 right?
00:28:28 A. Correct.
00:28:28 Q. And is there a continuing obligation in Boston
00:28:33 Scientific to forward information that impacts the
00:28:38 safety of its product to the FDA under that requirement?
00:28:42 A. Yes.
00:28:43 Q. Doctor, in your opinion, did Boston Scientific
00:28:54 satisfy the regulations and satisfy its obligations to
00:29:02 Ms. Barba, and to the women of the consuming public to
00:29:06 provide a safe and nondefective product for permanent
00:29:17 implantation into her body?
00:29:19 A. No, it did the not.
00:29:23 MR. THOMPSON: Your Honor, that's all the
00:29:24 questions I've got. Thank you.
00:29:52 (Pause.)
00:29:55 CROSS EXAMINATION
00:29:55 BY MR. KEENAN:
00:30:06 Q. Dr. Parisian, I have to strike a balance here
00:30:09 to make certainly the jury can see this and you can?
00:30:13 A. Do you want me to move over some?